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Discussion following the Remarks of Theodore C. Theofrastous, Dr. Joseph J. Jankowski, and Mark Romoff

Discussion

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counterpart entities in the United States and get on with the kinds of partnerships that can really advance the Canada-United States agenda on the innovation front.

Thanks for listening.

DISCUSSION FOLLOWING THE REMARKS OF THEODORE C. THEOFRASTOUS, DR. JOSEPH J. JANKOWSKI, AND MARK ROMOFF

MS. LUSSENBURG: Questions, I guess. Henry, do you have a question?

DR. KING: Okay. I wanted to ask Ted a question. You handle commercialization of technology for the Cleveland Clinic. I believe I am right on that. There are a lot of competitors forgetting that innovation that was developed by the doctor there.

What are the standards by which you determine who gets what and have the standards worked out, in other words, in terms of your ultimate result?

MR. THEOFRASTOUS: Well, internally, the standard for distribution is a function of institutional policy, and that is actually the same at Case as well. At The Cleveland Clinic, the individual investigator receives 40 percent of the net proceeds, and it is only net really of patent expenses from the commercial application side.

In terms of the industry participants vying for the technology, it is really – you would think it is a lot easier than it is, frankly, to get folks interested, to get industry interested at an early stage, at least somewhat validated technology. That is where, frankly, I can see a real benefit for something like the OCE.

But it boils down to the best deal and what's going to be the best upside for the institution. It becomes a very corporate type decision. What is going to yield the best income? Which of the potential candidates is really going to take this to market and put the highest level of investment into it?

Does that answer your question?

DR. KING: Yes. Has it worked?

MR. THEOFRASTOUS: I think so. You know, the problem with success is creating our – and when we talk about conflicts of interest, we are kind of dealing with the fact that it has been successful. And the genesis of those Wall Street Journal articles was a very successful device that, you know, in the interest of moving the innovation forward, you have people that ultimately became very senior at this institution involved in and having a stake in the commercialization. They consult. They help.

They really – you know, they believe in it. They think it is a great device and God forbid it makes billions of dollars, and all of a sudden they are rich. It makes people very uncomfortable that the white tower has people in it that are really making a lot of money, but, in fact, our sort of proposition is that's the way it was structured. The system was supposed to do that.

So it has worked. We are just trying to figure out how we deal with our success now.

MS. LUSSENBURG: I would have to go to Larry first if he still has a hangover question.

Were your questions answered, or otherwise, I will move on.

MR. HERMAN: I just wanted to know, when Mark was talking about his programs, I just wanted to quantify them. That was the point, and I think you said you have a fund of \$34 million dollars that you can leverage through different partnerships to \$75[million?], which I gather come from other public agencies.

Is that correct?

MR. ROMOFF: Not always. In many cases, it is industry because in that money, we count the partnerships that we put in place in order to enable technology we develop. So if a company is putting in the \$50,000 I talked about, we are counting that \$50,000 in the revenue we generate. So some of it is tied by definition because it is for a specific project.

THE WITNESS: All right.

DR. KING: Michael?

MR. ROBINSON: Thank you.

A comment and two very short questions for Mark. This sounds sort of like nothing new for Ontario. I remember a thing called the Ontario Technology Fund, lots of high profile publicity, was Peterson's Government. Pat Lagudwa was making speeches all over town, 50 percent Government and 50 percent corporations for commercialization.

It was kind of a joke because I did the contracts for the first two MDS, SIEX and IMAX, both very successful. The Government having made the announcement had no idea how to really put it together in detail. So, myself and a Government lawyer who knew nothing about science, worked out the contract and sold it to the Government.

My comment is: It sounds like you are a heck of a lot better organized than the Peterson Government was and, of course, the Ontario Technology Fund having had a few successes, I guess it was Bob Ray that killed it, so it is good to see it back again in a new guise.

The question is this: Why is there no biotech in your five OCE portfolio list here? I would have thought there is a lot going on there in Ontario, number one.

And number two, do you know if that ridiculous law that we had on the books in Ontario is now gone, namely, that hospitals cannot own more than ten percent of the business corporation? Because this has been a huge problem for commercializing, for example, the stuff that is coming out of U of T, out of the Lunenfeld at Mt. Sinai, et cetera.

And I worked on a major thing there for proteomics, and it just drove us nuts. It just didn't make any sense at all. I was told that they were going to get rid of it, but I wonder if it is gone.

MR. ROMOFF: Honestly, I don't know. To come to your second question, I am not sure of that. Are you going to Bio in 2006 from here?

MR. ROBINSON: No.

MR. ROMOFF: Too bad because the premier is going to be there. You should ask him. I don't know the answer. Someone else may know, I don't know.

On the first one, as to why there is no center for biotechnology, I will give you two answers, maybe three: One, the organization as it is currently figured is a reflection of what was there before the merger, so part of my challenge now is to think through how we redesign the corporation, whether we reengineer it at all but how we might do that in order to tackle the issues of the day. That is number one. That is the part – what you are seeing here is a bit of a legacy.

The second thing is, although we do not have a center for biotechnology, we spend an enormous amount of money and are engaged in a large number of, in fact, life sciences and biotechnology projects. We are not into big pharmaceuticals, but we are into a whole bunch of things. Photonics is probably the one that has the most obvious number of activities involved with the university hospitals network, for instance, in Ontario doing some really interesting research that is all about life sciences.

Our materials and manufacturing folks are working with the University of Toronto, tissue engineering projects, advanced polymers as vehicles for delivering medication internally; there are a whole bunch.

Of course, communications and IT guys are working on things, which you might not consider in this field, but it is all about the security of medical records so we are, in fact, playing on this agenda, and the other thing we are doing, which is very interesting, is we are engaged now in biotechnology and the automotive sector, bringing those two together, bringing those two together, sort of like tech-ionic plates, ones you normally would not think would come together, and maybe that's why you get some really interesting innovation.

So we have got a bio-car project under way at the moment. So it is bringing together developments in the industry sector and the auto sector to produce lighter, cheaper vehicles. So we are playing there. It is just not obvious from the way in which we are structured.

The last thing I would say is that while its mandate is in a state of evolution, we are partnering close with MARS, and they are very much in the agenda of life sciences but not really in the business at the moment of commercializing technology.

Where they are going to go over time is a bit unclear, but we are collaborating with them on a number of things, and wherever they go, we are going to be going there with them. So stay tuned with them on that front.

MS. LUSSENBURG: This gentleman over here had a question. I am sorry; I do not know your name. Mike is coming.

MR. BARBER: That would be Doug Barber.

MS. LUSSENBURG: Doug Barber. Thank you.

MR. BARBER: I have a couple of questions for you, Mark, and just to comment on Mark, years ago Mark threw fantastic parties for our customers in Genim. It is my claim to fame. Genim has done as high as 38 percent of its total business in Japan. So it was pretty successful, and we appreciated that, and we are kind of glad we have got Mark back.

MR. ROMOFF: It took more than a party.

MR. BARBER: The question I have is do you see the OCE as a developer of a culture of commerce? Also, I have a kind of a second question about those 2,600 that you had last year, researchers: Does that include the students?

MR. ROMOFF: It does include the students. That is the first thing. On the other side, I do not know whether – we probably do not mean something different when we say a culture of commerce and a culture of innovation. I think if we just had the culture would be great. And I see OCE playing right at the center of that agenda.

I mean, we are positioning ourselves to actually be the lead voice in Ontario for that agenda but, more importantly, to be out there working in the business community. But, you know, it is in a sense at the level what we are calling the street, the people who actually really either make decisions or influence decisions in order to really bring home the critical need for innovation and technology development and people development, home grown in Ontario and keep them in Ontario.

So my answer to that is, yes, and I know it is of huge interest for you, and there is an area where we might just be able to reconnect, Doug, in a way that will make a difference because I know it is a passion of yours.

MS. LUSSENBURG: Mr. Elmer. Is that right?

MR. ELMER: Yes.

MS. LUSSENBURG: All right.

MR. ELMER: I have two questions really: One is: Do you have an IP policy with respect to the allocation of IP rights with your collaborators, and if you do not have a policy, I think you said something – I am not sure I heard it correctly – but do you get involved in the allocation of those rights, and how are those rights ultimately allocated?

MR. ROMOFF: Are you talking to Ted or talking to me?

MR. ELMER: No. I was talking to you.

MR. ROMOFF: In the case of our activities, it depends on who the players are because in Ontario most universities, university policy dictates that the intellectual property rests with the university and in some cases with the researcher.

So we will normally work with what the norms are, and it is up to industry as to whether or not they are prepared to accept that arrangement. So, in fact, there is no rule of the game on this, except that the folks from within the Ontario Centers of Excellence come to the table for that negotiation with a complete open mind because, again, we do not have a vested interest.

What I want to make sure happens is that when we sign what we call a research collaboration agreement between a company and a researcher, what is really critical is that they need to have addressed the issue of intellectual property rights right up front at the beginning. That is the last thing you want to be negotiating down the road, so that is how we play.

MS. LUSSENBURG: The gentleman up in the back.

MR. TSAI: I am James Tsai. Just a general question directed, I guess, more towards Professor Theofrastous. You were talking about the pharmaceutical companies and the high costs that go into that.

Regarding world and intellectual property rights, I believe TRIPS article 66 said that the Government should give incentives to transfer the technology to less developed countries, and this has been a big topic with antibacterial-viral medication in Africa so on and so forth.

I was just wondering if any of the panelists can comment on what Governmental mechanisms there are in terms of financing and providing incentives to transfer technology or to develop.

MR. THEOFRASTOUS: I think that is an issue where you still sort of have to stay tuned. Unfortunately, that is on the back end of product development typically where all of those millions/billions of dollars have been spent, and you know, the market forces of pricing even between North - America - I'm sorry - between the United States and Canada are interesting, the calculus of pricing in a market where there is otherwise no demand for a product that is criminally needed; more where I have seen the debate going, letting - treating it more as a market issue than something that is sort of federally mandated.

But with that said, I think you can expect the sort of general tenor of the discussion somewhere between no and hell no, in part, because - and I think this is the problem with that particular species of very forward looking policy - ultimately, a corporation has an obligation to the shareholders, and the shareholders don't benefit necessarily by giving away the assets that cost so much money to create.

And I am not here to speak for capitalism generally, but I think that's the dynamic that makes it difficult to be really aggressive in that area.

MS. LUSSENBURG: Dick?

MR. CUNNINGHAM: I may have missed it in your earlier presentation, but my experience with the European system of doing this sort of thing, one of the criteria that has to be met is the determination that the funding could not be obtained from private resources.

Just parenthetically, that is a terrible criterion for them because it hangs under the countervailing authority and the WOD rules, but that's all right.

Is that a factor that you look at, and if so, is that something that you are insidious about? Is it a real factor, or does it matter at all?

MR. ROMOFF: If you are asking in my case it does not matter at all. We are judging every opportunity on the merit of the opportunity, and we also have a peer review process for the research monies we get engaged in.

And it mirrors the ones Rich spoke about earlier, which it is compromised of researchers who are looking at the merit of the science and the business community, who are looking at the commercial potential of the innovation.

MR. THEOFRASTOUS: I would add on the United States side there are actually, I think, several programs that are spiritually kindred with the OCE program. In the State of Ohio, the Ohio Department of Development has several programs, such as the third frontier program and the biomedical research and technology transfer program. These programs ultimately allocate ultimately many millions of dollars to early stage technology that is cannot be financially backed. But, frankly, the grant process is one where you have to demonstrate that if you get to the other end of it, it would be completely financially viable.

And, at least, the rhetoric has been one around even a return on that investment from the stay, not that they get a direct return on the investment, but they want to see that they are funding winners, and, in fact, they have even kicked – the BRTT program, they have even kicked that out to the National Academy of Sciences, to make sure that it is world class, it is going to work. They do not want the money going into areas that are not a good, you know, sort of financial bet.

In fact, the most recent program is even pushing state funds into the private equity sector, providing matching funds for the private equity world to go out and decide if these are good investments.

MS. LUSSENBURG: The gentleman up in the far right corner.

MR. DORCHAK: Andy Dorchak.

MS. LUSSENBURG: Sure. Go ahead.

MR. DORCHAK: This is for Ted, and I will assume your approach is correct and still has potential for public relations nightmares like learning that pharmaceutical companies pay for staff that will affect direct investing. Is that a market issue or legal issue?

MR. M.m. BURG: Well, both the FDA and NIH have struggled with conflicts of interest themselves, and in essence, the approach has really sort of been to disavow any of those relationships and shed them.

I think the downside for anybody in this room that has ever been involved in the process of taking a product through the Food and Drug Administration, it is hard. It is expensive. It is a little bit opaque. And so to the extent you get a person on the other end of that equation who is really trying to help you and willing to spend some time, maybe even their own time to understand the science well enough to get you through this maze, it is hugely valuable, and the question is, you know, should there be some level of compensation for that sort of off-the-clock help or not? I think the typical or the current tenor is no. Does that answer your question?

DR. JANKOWSKI: I would weigh in two things there: It will be a market force. At some point it hurts to have a Vioxx on the market if you have to recall it, about \$29 billion dollars worth of hurt, but secondly – and Case actually hosted yesterday one of the real watchdogs of the pharmaceutical industry, famous UCSF Professor named Dr. Nearri, and he is very anti-pharmaceutical for lack of a better term, and you need that voice.

And you are right, it does garner public spectacle, and at the same time, if you really look back and you say okay, greed and motivation such as this and interactions with the FDA that are now even being policed but even prior to that policing, look how good our drugs are in reality. How many Vioxxes do you actually have?

How many deaths off drugs relative to the good do they bring? You know, one out of 100 drugs may incite some sort of scandal, and it does not mean you just let the system go, but I think it is more of a hype in media activity than it really is a concern of the three-tiered system that we discussed today.

MR. THEOFRASTOUS: I guess I would add also to the extent the agencies are trying to figure this out themselves, if they move too erratically, it is going to have, it is going to have its own chilling effect on innovation. I worked with a small company, a small spinal disk replacement company that was looking at what they thought would be a \$4 million-dollar clinical trial with a ratcheting up with the safety concerns on the FDA. Now they are looking at literally a \$38 million-dollar clinical trial, and they don't have the money. So this may actually not go forward in the United States

MS. LUSSENBURG: If I may comment, it seems to me when we talk about conflict of interest that we have very different issues at very different levels. The fact that someone in the FDA might receive financial reward for approving a product or medicine is an inherent conflict of interest, quite different from when you started your remarks, and I suspect they were made to stir the pot; that the motivation is not pristine when people are seeking to make money out of the research they do.

It seems to me in our discussion about innovation and financing is that there has to be a financial motivation. Some people are motivated purely

about altruism and the good of human mankind, but, honestly, that is a very small margin of our population.

Most people work in research out of intellectual curiosity but also because they have to put bread on the table, pay the mortgage, look after their kids, et cetera, and that in my view is not necessarily a bad thing. That is what drives our economy.

Entrepreneurship, which is something we seem to be lacking in Ontario – and entrepreneurship and innovation seem to go hand in hand – is, in part, because we are not sufficiently motivated by that dollar, and is it such a bad thing as long as you have the checks and balances and perhaps transparency as opposed to the opaqueness that you were referring to?

I guess like everyone I think it is a bad thing to have opaqueness in any regulator or to give a financial reward to a regulator to approve your product one way or another, directly or indirectly, but on the other end, before they get there, surely to God we have to incent these people.

MR. THEOFRASTOUS: Yeah. I think the challenge is to the extent you have got a previously fairly esoteric science, how are you going to take the science forward without the investigator who is supposed to be the ultimate objective scientific arbiter of the effectiveness and safety of this device, how are you going to feel comfortable with the fact that they are going to get a gigantic upside if they are successful?

I think it is manageable, and I think there are a number of ways it can be handled, but the way it stands right now, we are all a little surprised that the surgeon that is implanting a device, if it is ultimately successful, that they will be extremely wealthy, and maybe we just should not be surprised.

DR. KING: We may have that for a topic next year.

MS. LUSSENBURG: Good.

DR. KING: I think we ought to cut it off.

MS. LUSSENBURG: Okay. Thank you, all. Thank you to our speakers.

I think you all know there were handouts, and they are on the table outside if you did not pick up the handout. I meant to mention that at the beginning, but just to make sure that if you don't have a handout, please help yourself.

Thanks very much to Joe, Mark, Ted, that was great.

DR. JANKOWSKI: Thank you.

(Session concluded.)